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October 22, 2003

TO: Examiner Horlick (TC1600)

GROUP: 1637

FAX NUMBER: 703-872-9306

ATTORNEY DOCKET NO.: DEX-0271

SERIAL NO.: 10/001,883

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MESSAGE: Attached please find Amendment Transmittal Letter, Reply to Restriction Requirement and Certificate of Transmission by Facsimile.

Kathleen A. Tyrrell, Registration No. 38,350

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CERTIFICATE OF TRANSMISSION BY FACSIMILE (37 CFR 1.8) Applicant(s): Macina et al.			Docket No. DEX-0271
Serial No. 10/001,883	Filing Date November 20, 2001	Examiner Horlick, Kenneth R.	Group Art Unit 1637

Invention: **Compositions and Methods Relating to Colon Specific Genes and Proteins**

I hereby certify that this **Reply to Restriction Requirement**
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AMENDMENT TRANSMITTAL LETTER (Large Entity) Applicant(s): Macina et al.	Docket No. DEX-0271

Serial No.	Filing Date	Examiner	Group Art Unit
10/001,883	November 20, 2001	Horlick, Kenneth R.	1637

Invention: **Compositions and Methods Relating to Colon Specific Genes and Proteins**

TO THE COMMISSIONER FOR PATENTS:

Transmitted herewith is an amendment in the above-identified application.

The fee has been calculated and is transmitted as shown below.

CLAIMS AS AMENDED

	CLAIMS REMAINING AFTER AMENDMENT		HIGHEST # PREV. PAID FOR		NUMBER EXTRA CLAIMS PRESENT		RATE	ADDITIONAL FEE
TOTAL CLAIMS	19	-	20	=	0	x	$18.00	$0.00
INDEP. CLAIMS	2	-	3	=	0	x	$86.00	$0.00
Multiple Dependent Claims (check if applicable) ☐								$0.00
TOTAL ADDITIONAL FEE FOR THIS AMENDMENT								$0.00

☒ No additional fee is required for amendment.

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Dated: **October 22, 2003**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Attorney Docket No.:	**DEX-0271**
Inventors:	**Macina et al.**
Serial No.:	**10/001,883**
Filing Date:	**November 20, 2001**
Examiner:	**Horlick, Kenneth R.**
Group Art Unit:	**1637**
Title:	**Compositions and Methods Relating to Colon Specific Genes and Proteins**

Certificate of Facsimile Transmission

I hereby certify that this document is being facsimile transmitted to the Patent and Trademark Office on the date shown below.

On October 22, 2003

Kathleen A. Tyrrell, Registration No. 38,350

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Dear Sir:

Reply to Restriction Requirement

This is a reply to the Restriction Requirement mailed September 22, 2002 setting a one (1) month statutory period for response. Please enter the following remarks into the record.

Amendments to the claims are reflected in the listing of claims which begins on page 3 of this paper.

Remarks begin on page 7.

This listing of the claims will replace all prior versions and listings of claims in the application:

Listing of the claims:

Claim 1 (currently amended): An isolated nucleic acid molecule comprising

(a) a nucleic acid molecule ~~comprising a nucleic acid sequence that encodes an amino acid sequence of SEQ ID NO: 74 through 137~~ that due to the degeneracy of the genetic code corresponds to a coding region defined by SEQ ID NO: 1 through 73;

(b) a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 through 73;

(c) a nucleic acid molecule that selectively hybridizes to the nucleic acid molecule of (a) or (b); or

(d) a nucleic acid molecule having at least ~~60%~~ 75% sequence identity to the nucleic acid molecule of (a) or (b).

Claim 2 (original): The nucleic acid molecule according to claim 1, wherein the nucleic acid molecule is a cDNA.

Claim 3 (original): The nucleic acid molecule according to claim 1, wherein the nucleic acid molecule is genomic DNA.

Claim 4 (original): The nucleic acid molecule according to

claim 1, wherein the nucleic acid molecule is a mammalian nucleic acid molecule.

Claim 5 (original): The nucleic acid molecule according to claim 4, wherein the nucleic acid molecule is a human nucleic acid molecule.

Claim 6 (original): A method for determining the presence of a colon specific nucleic acid (CSNA) in a sample, comprising the steps of:

(a) contacting the sample with the nucleic acid molecule according to claim 1 under conditions in which the nucleic acid molecule will selectively hybridize to a colon specific nucleic acid; and

(b) detecting hybridization of the nucleic acid molecule to a CSNA in the sample, wherein the detection of the hybridization indicates the presence of a CSNA in the sample.

Claim 7 (original): A vector comprising the nucleic acid molecule of claim 1.

Claim 8 (original): A host cell comprising the vector according to claim 7.

Claim 9 (original): A method for producing a polypeptide encoded by the nucleic acid molecule according to claim 1, comprising the steps of (a) providing a host cell comprising the

nucleic acid molecule operably linked to one or more expression control sequences, and (b) incubating the host cell under conditions in which the polypeptide is produced.

Claim 10 (original): A polypeptide encoded by the nucleic acid molecule according to claim 1.

Claim 11 (original): An isolated polypeptide selected from the group consisting of:

(a) a polypeptide comprising an amino acid sequence with at least 60% sequence identity to of SEQ ID NO: 74 through 137; or

(b) a polypeptide comprising an amino acid sequence encoded by a nucleic acid molecule comprising a nucleic acid sequence of SEQ ID NO: 1 through 73.

Claim 12 (original): An antibody or fragment thereof that specifically binds to the polypeptide according to claim 11.

Claim 13 (original): A method for determining the presence of a colon specific protein in a sample, comprising the steps of:

(a) contacting the sample with the antibody according to claim 12 under conditions in which the antibody will selectively bind to the colon specific protein; and

(b) detecting binding of the antibody to a colon specific protein in the sample, wherein the detection of binding indicates the presence of a colon specific protein in the sample.

Claim 14 (previously amended): A method for diagnosing and monitoring the presence and metastases of colon cancer in a patient, comprising the steps of:

(a) determining an amount of the nucleic acid molecule of claim 1 or a polypeptide of claim 6 in a sample of a patient; and

(b) comparing the amount of the determined nucleic acid molecule or the polypeptide in the sample of the patient to the amount of the colon specific marker in a normal control; wherein a difference in the amount of the nucleic acid molecule or the polypeptide in the sample compared to the amount of the nucleic acid molecule or the polypeptide in the normal control is associated with the presence of colon cancer.

Claim 15 (previously amended): A kit for detecting a risk of cancer or presence of cancer in a patient, said kit comprising a means for determining the presence the nucleic acid molecule of claim 1 or a polypeptide of claim 11 in a sample of a patient.

Claim 16 (original): A method of treating a patient with colon cancer, comprising the step of administering a composition according to claim 12 to a patient in need thereof, wherein said administration induces an immune response against the colon cancer cell expressing the nucleic acid molecule or polypeptide.

Claim 17 (original): A vaccine comprising the polypeptide or the nucleic acid encoding the polypeptide of claim 11.

REMARKS

Claims 1-17 are pending in the instant application. Claim 1 has been amended. Support for amendments to claim can be found in the specification at page 21, lines 25-28, page 113, lines 15-16 and page 143, lines 2-6. Thus, no new matter is added by this amendment.

Claims 1-17 have been subjected to a Restriction Requirement as follows:

Group I, claims 1-5, 7-9 and 15 (partial), drawn to nucleic acids, vectors, host cells and methods of making a polypeptide, classified in class 536, subclass 23.1, and class 435, subclasses 69.1, 320.1 and 325, for example;

Group II, claim 10-11, drawn to polypeptides, classified in class 530, subclass 350, for example;

Group III, claims 12 and 15 (partial), drawn to an antibody, classified in class 530, subclass 387.1, for example;

Group IV, claims 6 and 14 (partial), drawn to a method of determining the presence of a nucleic acid, classified in class 435, subclass 6;

Group V, claims 13 and 14 (partial), drawn to a method of determining the presence of a polypeptide, classified in class

435, subclass 7.1, for example;

Group VI, claim 16, drawn to a method for treating a patient with colon cancer by administering an antibody, classified in class 514, subclass 2, for example;

Group VII, claim 17(partial), drawn to a vaccine comprising a polypeptide, classified in class 514, subclass 2; and

Group VIII, claim 17 (partial), drawn to a vaccine comprising a nucleic acid, classified in class 514, subclass 44.

The Examiner suggests that these Groups are distinct.

Specifically, with respect to Groups I, II, III, VII and VIII, the Examiner suggests that the claims are drawn to different products having different structures and functions.

With respect to Groups I and IV, and Groups III and (V,VI), the Examiner has acknowledged their relationship as product and process of use. However, the Examiner suggests that the Groups are distinct because the products can be used in materially different methods or processes.

With respect to Groups I and (V, VI), Groups II and (IV, V and VI), Groups III and IV, Groups IV-VI, and Groups (IV-VI) and (VII,VIII), the Examiner suggests that the Groups are unrelated because the different Groups are not required for one another.

Further, the Examiner suggests that each of Groups I-VIII

are drawn to a multitude of nucleic acids, polypeptides, and antibodies thereto which are independent and distinct. Thus, the Examiner is also requiring election of a single nucleic acid, polypeptide or antibody.

Applicants respectfully traverse this Restriction Requirement.

MPEP §803 provides two criteria which must be met for a restriction requirement to be proper. The first is that the inventions be independent or distinct. The second is that there would be a serious burden on the Examiner if the restriction is not required. A search of prior art relating to an elected nucleic acid, polypeptide or antibody would also reveal any references teaching uses for the nucleic acid, polypeptide or antibody. Accordingly, Applicants believe that searching of all the claims, at least when limited to elected nucleic acids or polypeptides is overlapping and would not place an undue burden on the Examiner if the Restriction is not made.

Thus, since this Restriction Requirement does not meet both criteria as set forth in MPEP § 803 to be proper, reconsideration and withdrawal of this Restriction Requirement is respectfully requested.

In addition, with respect to the election of a single

sequence, MPEP § 803.04 clearly states that a reasonable number of nucleotide sequences, normally ten sequences, can be claimed in a single application. Accordingly, withdrawal of this sequence election requirement and reconsideration to include a more reasonable number of at least 10 sequences in accordance with MPEP § 803.04 is also respectfully requested.

However, in an earnest effort to advance the prosecution of this case, Applicants elect Group I, claims 1-5, 7-9 and 15, SEQ ID NO:66, with traverse.

Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

Respectfully submitted,

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Date: October 22, 2003

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